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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,686	02/10/2004	Gregory B. Altshuler	105090-0237	3811

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EXAMINER	
JOHNSON III, HENRY M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,686	ALTSHULER ET AL.	
	Examiner	Art Unit	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15,17-20,22-24,26 and 28-40* is/are rejected.

7)☒ Claim(s) *14,16,21,25 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *020206*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 4/67/2006 have been fully considered but they are not persuasive.

The invention of Chen et al. teaches an embodiment with a source coupled to an optical fiber that delivers radiation around a "U" shaped structure that clearly irradiates selected areas in predetermined directions. Radiation from the fiber is controlled by nicks, scratches, dimples or grooves in the cladding (partial etch).

The invention of Muller radiates through and between the bristles of the manually directed brush. A user selectively radiates in predetermined directions, as the brush is oriented within a mouth. By virtue of its size and portability, the device is capable of selectively radiation a plurality of regions in predetermined directions.

Applicant's arguments with respect to the rejection of claim 19 are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Iimura.

Applicant's arguments regarding Mendes et al. are not persuasive. The device is clearly capable of delivering radiation in predetermined directions as it is moved by a user. It can also be argued that LEDs inherently produce divergent beams. Any divergence would yield multiple directions for the radiation.

The motivation to combine Muller and Altshuler et al. is provided by Altshuler et al. The motivation is not limited to a single prior art reference.

Applicant's arguments with respect to claims 21, 25 and 27 have been fully considered and are persuasive. The rejection has been withdrawn.

Applicant's arguments with respect to claims 22, 24, 26, 34 and 39 have been considered but are moot in view of the new ground(s) of rejection.

The provisional obvious double patenting rejection have been tentatively withdrawn pending further evaluation as the claims in the co-pending applications are modified.

Specification

Full continuation information is required including the application number, date filed and status; e.g. now U.S. Patent , now abandoned, etc.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite, as sources cannot be transmitted. The radiation from a source may be transmitted in different directions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-9, 23, 28-33, 35 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/06456 to Chen et al. Chen et al. teach an apparatus employing light therapy to treat oral conditions (abstract) including a mouthpiece that surrounds the teeth and gums (Fig. 2) that may be comfortably left inside a patient's mouth for extended times (page 2, lines 32-35) and is made from an elastomeric material such as silicone (page 5, line 8). This is interpreted as a compliant mouthpiece. The radiation source is disclosed as an LED, laser diode, gas discharge lamp or filament bulb (page 3, lines 30-32). The source may be mounted on the mouthpiece or located external to the mouthpiece with the radiation delivered via fiber optics (optical element). The means for delivery may include diffusing material (page 3, line 25). The optical fibers deliver the radiation in different directions (page 6, lines 13-15) and the cladding of the fiber may be nicked, scratched, or have dimples or grooves on the cladding (page 8, lines 20-30), the cladding features interpreted as partial etchings. Portions of the mouthpiece may be highly reflective (page 7, line 21). The sources mounted around the mouthpiece clearly radiate in different directions. Chen et al. incorporates by reference U.S. Patent 5,445,608 that teaches the use of either an internal or external array of light sources and allows use of LEDs or laser diodes operating at two or more wavelengths, and the ability to selectively activate (controller) the sources operating at a given wavelength or waveband as desired, so that the light at the different wavelengths or wavebands is provided to the treatment site either sequentially or simultaneously from the light sources (Col. 8, lines 37-45). The sources may be controlled by monitoring the temperature rise of the tissue (diagnostic sensor) (Col. 8, line 8). The current regulation will control the power of the light source. Lacking a definite structure for the radiation elements, one LED on one side of the mouthpiece is interpreted as the first radiating element and one on the opposite side as the second radiating

element (Fig. 6), the second element clearly radiating in a direction other than that of the first element. The LEDs have a divergent beam (Fig. 6A) that radiates in multiple directions. The '608 reference further teaches that waste heat produced by the array of LEDs or LDs disposed on the probe can be employed to augment the PDT by increasing the temperature of the tissue at the treatment site (abstract) and the use of heat sinks (Fig. 1) for heat dissipation. Ports are disclosed in the '408 patent for conveying a photoreactive agent from a photoreactive agent reservoir to the target site.

Claims 1-9, 31, 34 and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,443,978 to Zharov. Zharov teaches a photomatrix device for irradiation of tissue using multiple LEDs that may be of different wavelengths (Col. 12, lines 1-5). Zharov discloses multiple configurations of the photomatrix for treating various areas of a body including for use in a mouth (Col. 12, line 41), such unit capable of radiating objects with the oral cavity including facial areas. Fluences of 500 mW/cm^2 are able to penetrate a mucosal liming. Lacking a definite structure for the radiation elements, any LED or group of LEDs can be interpreted as the first and second radiation emitting elements with the selected elements radiating in different directions. Lenses (Col. 3, lines 61-66) are disclosed associated with the LEDs that may provide coverage of up to 180 degrees (multiple directions). Control is disclosed with various pulse widths and repetition rates (Col. 3, lines 15-25). The device may include an ultrasonic module (Claim 61), the ultrasonic also interpreted as a vibrating element. Zharov teaches the device being shaped to conform to a selected area which is interpreted to include any body area, including lips.

Claims 1, 10-13, 15, 17 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,862,771 to Muller. Muller teaches a toothbrush with a head with bristles and a

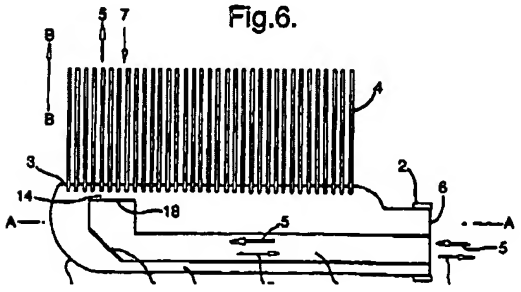


Fig.6.

radiation source in a handle. The location in the handle is disclosed as convenient if the toothbrush is an electrical toothbrush, i.e. having electrical drive means to move the cleaning bristles in a tooth cleaning operation. The electric drive is interpreted as a vibrating mechanism. The radiation is directed in a direction parallel to the bristles either between the bristles or through the optically transparent bristles, thus teaching a plurality of emitters (Fig. 6). The bristles are interpreted as optical elements and capable of radiating in multiple directions as the device is moved by a user. A reflecting surface directs the radiation to the bristles (Fig. 6, # 17). The apparatus is clearly capable of radiating any area within an oral cavity. The radiation source may be a light emitting diode (LED) of known type and filters and mirrors are disclosed in the optical path. A lens may be used in the optical path (Col. 12, line 38) and this is interpreted as a diffuser as lenses may diverge a beam, effectively diffusing the beam. The bristles have a core made of a transparent plastic material, surrounded by a sheath also of a transparent plastic material with a lower refractive index than that of the core (reflective). Alternatively the sheath may be thin coating of a shiny metal, e.g. 2-3 microns thick (col. 13, lines 12-17). The bristles inherently have a shape that transmits radiation upon contact or the device would not be operable. The head is disclosed as being detachable (Col. 8, line 55).

Claims 1, 10-13, 15, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,239,442 to Iimura. Iimura discloses a light emitting cleaning tool that may be made very small (Col. 7, line 45). The background discloses toothbrushes for cleaning, implying the tool can at least partially fit in a mouth. The light source may be located in a handle and deliver radiation to the head and bristles, which when moved by a user produces radiation in multiple directions. The head is the body and is coupled to a first radiation emitting element (Fig. 6). Particles to scatter and diffuse the radiation are disclosed (Col. 5, lines 33-37) in the head thereby causing a portion of the radiation to transmit in a direction that is not parallel to the

bristles (Fig. 8) and the bristles are disclosed as having a light reflecting means (claim 7). The bristles have a shape and radiate so the shape inherently allows radiation.

Claims 1, 22, 24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,572,637 to Yamazaki et al. Yamazaki et al. teach a handheld light treatment device with a cylindrical adjuster (Fig. 2, # 20) to delivery the radiation to an area. The adjuster is interpreted as being capable of insertion into a mouth. The device being handheld is able to direct radiation in multiple directions as desired by a user. The adjuster may be equipped with a microswitch responsive to adjuster's touching the skin for making the electric power supply to turn on, and responsive to adjuster's leaving the skin for making the electric power supply to turn off (Col. 3, lines 23-30). The radiation source is cooled by a heat sink (Fig. 2, # 18) and a fan is provided in the handheld unit (Fig. 2, # 14). The heat sink, by definition, is a thermally conductive element. Since the cooling means are all within the handheld unit, it is inherent the handle receives some of the heat.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller as applied to claim 19 above and further in view of U.S. Patent 6,273,884 to Altshuler et al. Muller is discussed above, but does not disclose inhibiting radiation when not in contact with tissue. Altshuler et al. teach a tissue treatment apparatus and the concept of total internal reflection. The optical delivery channel is treated to normally have total internal reflection so that light or other radiation entering the channel is reflected internally, however, when lens (output face) is in contact with a patient's skin, the total internal reflection at the skin-contacting surface is broken due to the change of index of refraction at this surface so that light energy is emitted into the patient's skin (Col. 16, lines 25-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the technique of modifying the index of refraction of the light channel as taught by Altshuler et al. in the invention of Muller to limit the radiation to the oral cavity as a safety consideration as suggested by Altshuler et al. The concepts of total internal reflection are well known as further substantiated by U.S. Patent 6,126,655 to Domankevitz et al.

Allowable Subject Matter

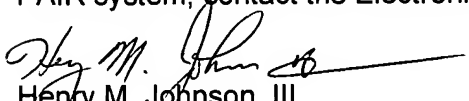
Claims 14, 16, 21, 25 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III
Primary Examiner
Art Unit 3739